January 12, 2024

Owens & Minor (O&M) Halyard, Inc.
Anureet Singh
Regulatory Affairs Manager
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K233022
Trade/Device Name: Halyard Fluidshield 3 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, Orange, Regular and Small, Halyard Fluidshield 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and So Soft Lining, Orange, Regular and Small, Halyard Fluidshield 2 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, White, Regular and Small
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: MSH
Dated: January 10, 2024
Received: January 10, 2024

Dear Anureet Singh:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233022

Device Name
Halyard Fluidshield 3 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, Orange, Regular and Small, Halyard Fluidshield 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and So Soft Lining, Orange, Regular and Small, Halyard Fluidshield 2 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, White, Regular and Small

Indications for Use *(Describe)*
The HALYARD FLUIDSHIELD N95 Particulate Filter Respirator and Surgical Mask family is intended for use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K233022

510(k) Owner: O & M Halyard, Inc.
9120 Lockwood Boulevard
Mechanicsville, VA 23116
Phone: 804-723-7000/800-488-8850
Fax: 804-723-7100

Regulatory Contact: Anureet Singh
Regulatory Affairs Manager

Date of Summary: 12 January 2024

Device Trade Name: HALYARD* FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, Orange, Regular and Small,

HALYARD* FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and So Soft Lining, Orange, Regular and Small,

HALYARD* FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with So Soft Lining, White, Regular and Small

Common Name: Surgical Respirator

Classification Name: Surgical Respirator (21 CFR 878.4040, Product Code MSH)

Predicate Device: PFR95™ Particulate Filter Respirator and Surgical Mask Regular Size, K974068

Device Description: Respirator consisting of nonwoven inner facing, filter media(s), a fluid barrier film, and an outer facing. It covers the nose and mouth of the wearer and is held in place with two synthetic elastic headbands, conforming to the curvature of the wearer's nose with a malleable nosepiece.

Device Model Information:

Model Number	Name	Color	Size	ASTM F1862	Individually Packaged	Dispenser Quantity	Case Quantity
46827	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	Orange	Small	160mmHg	No	35	210
76827	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	Orange	Small	160mmHg	No	35	315
46828	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical	Orange	Small	160mmHg	Yes	35	210

	Mask with SO SOFT* Lining						
46867	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	Orange	Small	160mmHg	No	35	210
76867	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	Orange	Small	160mmHg	No	35	315
46727	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	Orange	Regular	160mmHg	No	35	210
76727	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	Orange	Regular	160mmHg	No	35	315
46728	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	Orange	Regular	160mmHg	Yes	35	210
46767	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	Orange	Regular	160mmHg	No	35	210
76767	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining	Orange	Regular	160mmHg	No	35	315
62355	FLUIDSHIELD* 2 N95 Particulate	White	Small	120mmHg	No	50	300

	Filter Respirator and Surgical Mask with SO SOFT* Lining						
62126	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining	White	Regular	120mmHg	No	50	300

Note: All devices are provided non-sterile

Indication for Use: The HALYARD* FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask family is intended for use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

Comparison of Device Technological Characteristics:

	Subject Device **HALYARD* FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask (K233022)**	**Predicate** **Tecnol PFR95™ Particulate Filter Respirator and Surgical Mask (K974068)**	**Comparison Result**
Manufacturer	O&M Halyard, Inc.	Tecnol Medical Products, Incorporated	Different
Device Model Numbers	46827 & 76827 46828 46867 & 76867 46727 & 76727 46728 46767 & 76767 62355 62126	47119-110 47119-210 46717 46737 47119-114 47119-174 47119-214 47119-274 46817 46827 46837 46867	Similar
Common or Usual Name	Surgical Respirator	Surgical Respirator	Same
Classification	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product Code	MSH	MSH	Same
Indication for Use	The HALYARD* FLUIDSHIELD* N95 Particulate Filter Respirator	The PFR95™ Particulate Filter Respirator and Surgical Masks are intended	Similar

	and Surgical Mask family is intended for use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.	for use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.	
Device Description and Materials	Respirator consisting of nonwoven inner facing, filter media(s), a fluid barrier film, and an outer facing. It covers the nose and mouth of the wearer and is held in place with two synthetic elastic headbands, conforming to the curvature of the wearer's nose with a malleable nosepiece.	Respirator consisting of nonwoven inner facing, filter media(s), a fluid barrier film, and an outer facing. It covers the nose and mouth of the wearer and is held in place with two synthetic elastic headbands, conforming to the curvature of the wearer's nose with a malleable nosepiece.	Same
Method for Bonding	Ultrasonic	Ultrasonic	Same
Distribution	Non-Sterile and Over-the-Counter	Non-Sterile and Over-the-Counter	Same
Single Use Device	Yes	Yes	Same

Comparison of Specification Performance and Biocompatibility:

	Subject Device HALYARD* FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask (K233022)	**Predicate Tecnol PFR95™ Particulate Filter Respirator and Surgical Mask (K974068)**	**Comparison Result**
Filtration Efficiency	NIOSH certified	NIOSH certified	Same
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result, 160mmHg (Fluidshield 3 models: 46827, 76827, 46828, 46867, 76867, 46727, 76727,	Pass	Standard did not exist	Different

46728, 46767, 76767) ASTM F1862			
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result, 120mmHg (Fluidshield 2 models: 62355, 62126) ASTM F1862	Pass	Standard did not exist	Different
Biocompatibility: Non-sensitizing Non-cytotoxic Non-irritating	Pass	Pass	Same
Flame spread, Class I	Pass	Standard did not exist	Different
Bacterial Filtration Efficiency ASTM F2101	Pass BFE ≥ 98%	Standard did not exist	Different
Particulate Filtration Efficiency ASTM F2299	Pass PFE ≥ 98%	Standard did not exist	Different

Summary of Non-Clinical Performance Testing

Performance Testing (Bench):

Performance Characteristic	**Test Method**	**Acceptance Criteria**	**Result**
Filtration Efficiency	TEB-APR-STP-0059	Minimum efficiency for each filter of ≥95% (≤5% penetration)	Pass
Breathability	TEB-APR-STP-0007 and TEB-APR-STP-0003	Not exceeding 35mmH_2O for TEB-APR-STP-0007, Not exceeding 25 mmH_2O for TEB-APR-STP-0003	Pass
Fluid Resistance	ASTM F1862	Pass at 120mmHg Pass at 160mmHg	Pass
Flammability	16 CFR 1610	Class I Normal Flammability	Pass
Biocompatibility	ISO 10993-5 L929 MEM Elution Test	< Grade 2 (mild reactivity) Non-cytotoxic	Pass
Biocompatibility	ISO 10993-10 Guinea Pig Maximization test	No dermal erythemic response Non-sensitizing	Pass

Biocompatibility	ISO 10993-23 Intracutaneous Injection Test	Difference between test article and control article overall mean score ≤ 1 Non-irritating	Pass

Summary of Clinical Performance Testing:
Not applicable.

Conclusions: The conclusions drawn from the non-clinical tests demonstrate the subject device, the HALYARD* FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask family, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Tecnol PFR95™ Particulate Filter Respirator and Surgical Mask (K974068).